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J. Billingsley

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AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Breathable gas apparatus with Humidifier

This invention relates to breathable gas supply apparatus, and particularly but not exclusively to such apparatus for use in Continuous Positive Airways Pressure (CPAP) treatment of conditions such as Obstructive Sleep Apnea. It will be described herein in its application to CPAP treatment apparatus, but it is to be understood that the features of the invention will have application to other fields of application, such as mechanical ventilation and assisted respiration.

The advantages of incorporating humidification of the air supply to a patient are known, and CPAP machines are known which incorporate humidifying devices. One of the objects of the invention is to provide a simple and compact breathable gas supply apparatus incorporating a humidifier which is simple and economic in its construction, compact, and easy to use. Other objects and advantages of the invention will be described throughout the specification.

It is to be understood that apparatus described herein contains a number of advances on the prior art, many of which independent inventions, although they contribute together to the realisation of the general object expressed above.

The apparatus described herein incorporates novel aspects of architecture which contribute to a reduction in size compared with known units having similar performance. Techniques for noise reduction and damping are described which enable such a smaller machine to have noise performance which is at least as good as known lager machines.

The apparatus described achieves full integration of the humidifier with the flow generator, in the sense that air flow, electrical and, if required, data connection

between the flow generator and the humidifier are provided automatically upon the physical engagement of the two devices, without the need for any other process of interconnection.

In such an integrated device, provisions to guard against flowback of water from the humidifier tank to the flow generator are important, and novel sealing arrangements, and novel arrangements for minimising the occurrence of flowback while at the same time improving the uptake of water vapour in the humidifier are also described. The humidifier is readily detached and replaced on the machine, and has very few parts to be disassembled during cleaning.

Also described herein are improved, modular, devices for enabling data connection with the apparatus, including the connection of data storage devices such as memory cards, smart cards, communication ports and the like to be selectively attached by the user or by medical personnel.

The various aspects of the invention will now be described with reference to the accompanying illustrations, which show a presently proposed embodiment.

In the drawings:

Fig.1 is a general view of breathable gas apparatus embodying the various features of the invention;

Fig. 2 shows the flow generator of the apparatus;

Fig. 3 shows the humidifier unit;

Fig. 4 is a cutaway view of the flow generator;

Fig.5 is a rear view of the humidifier;

Fig. 6 is an exploded view of components of the flow generator;

Fig. 7 is an underneath view of a chassis forming part of the flow generator;

Fig. 8 is a rear view of the chassis;

Fig. 9 is a general view of a fan forming part of the flow generator;

Fig. 10 is an underneath view of the fan;

Fig. 11 is a cross-sectional view of the fan;

Fig. 12 shows the humidifier in partly disassembled state;

Fig. 13 is an underneath view of the tank of the humidifier;

Fig. 14 is an underneath view of the tank showing an alternative valve

Fig. 15 is a view of the tank cover

Fig. 16 is an underneath view of the tank cover

Fig. 17 is an underneath view of a modified tank cover, and

Figs. 18 to 21 show various modular connector arrangements.

The illustrated apparatus comprises a flow generator 50 and a humidifier 150, shown in their assembled condition in Fig. 1. As shown in Fig. 2, the flow generator engages with the separable humidifier at an engagement face 52, from which protrudes an air connector 53 for the delivery of air from the fan to the humidifier container, and electrical connectors 54 for the delivery of power to the humidifier heater described below.

The face 52 also carries a pair of slots 55 which are engaged by corresponding tongues 156 provided on the humidifier engagement face 157 (Fig. 5) by which the flow generator 50 and humidifier 150 are connected together, as will be described in more detail below.

Externally, the flow generator 50 is also provided with an LCD screen 58 and associated keys 59 by which the user can set the operating parameters of the unit.

The flow generator 50 has an external case of rigid plastics material moulded in two parts, a top case 60 and a bottom case 61. The lower edge of the top case 60 is stepped and flanged at 62 to mate with the periphery of the bottom case 61. Overmoulded with the rigid plastics body of the bottom case 61 is a rubber sealing flange 63, which locates between and seals against the cases 60 and 61 on the one hand, and the outer surface of a chassis 64 described further below.

Formed in the bottom case 61 by walls which join the outer wall of the case are the lower parts 65 and 67 of, respectively, a power supply cavity and a resonator cavity.

The upper parts 66 and 68 of these cavities are formed in the chassis 64, described below.

The chassis 64 is formed with a peripheral wall 69 flanged around its lower edge to engage with the inner periphery of the overmoulded sealing flange 63. The chassis 64 includes a downwardly extending fan cavity 70 in which is mounted the fan 90 described below. This cavity 70 is formed by moulded side walls 71 and base 72, which are formed by moulding thermoplastic around an inserted stainless steel liner 73. The fan cavity 70 opens to the upper surface of the chassis 64 to enable insertion of the fan 90, this opening being closed by a lid 74. Like the cavity 70, the lid 74 has an imbedded stainless steel plate insert moulded within a thermoplastics material, and at its edges the lid is provided with co-molded elastomer sealing edges. The formation of the cavity 70 by insert moulding from differing materials provides very effective acoustic damping, as does the combination by co-moulding of the hard and soft plastics described already and further described below. In this aspect of the present invention, the use of co-moulding or overmoulding in the combination of materials of different, preferably widely different, stiffness and different, preferably widely different, density has been found to be particularly advantageous in providing acoustic damping.

The upper part 66 of the power supply cavity is formed by a side wall 75 extending downwardly from the roof of the chassis 64, which sealingly engages the opposed wall of the lower portion 65 of this cavity. Preferably, the lower wall is provided for this purpose with a co-moulded or overmoulded rubber sealing flange 76 similar to the flange. The power supply compartment is thus sealed against the ingress of moisture from the interior of the unit in the case of backflow from the humidifier. Similarly, the air path is sealed from the power supply compartment. The interior is at the same time acoustically sealed from the power supply cavity, which may not be completely sealed from the exterior, due to the necessity of providing mains power input and low voltage power output to the humidifier, via connectors 77 and 79 mounted in apertures 78 and 80 respectively in the rear and front walls of the cavity, and if necessary the venting of the compartment to outside air for cooling.

Supported on the top of the chassis 64, in the space formed between the chassis and the top of the top case 60 is a printed circuit board 81 carrying the electronic control components of the unit. At the rear of the board 81 an edge connector 82 and a sliding connector 82A are accessible from a connector aperture 83 in the rear of the case 60, providing for modular connector arrangements to be described in more detail below.

Also provided in the rear wall of the top case is an air inlet 84, and this communicates with an air inlet passage 85 formed in the roof of the upper portion 66 of the power supply cavity, this passage in turn opening through the inner side wall of that cavity at 87 to the air space surrounding the fan cavity 70 in the interior of the unit. Air drawn into the unit by the fan will thus pass over the roof of the power supply and thereby assist in the dissipation of heat generated by the power supply.

A removable air filter body 85A containing a replaceable filter element attaches to the inlet 84, as shown in Figs. 2 and 6.

From the air space surrounding the fan cavity 70, inlet air passes to the fan cavity via an inlet tube 88 depending from a horizontal extension of the side wall 71 of the fan cavity.

The fan cavity and the space surrounding it and enclosed by the upper and lower cases form a pair of serially connected volume mufflers, and the dimensions of the aperture 88 and the air passage 85 are chosen to optimise the noise attenuation produced by these mufflers, within the constraint of avoiding unacceptable air flow restriction.

It will now be convenient to describe the features of the fan, which are shown in Figs. 9 to 11.

The fan 90 comprises a motor 91, preferably brushless DC motor, provided with a coaxial impeller 92, mounted vertically within a fan housing consisting of a cover 93 and a base 94. An air inlet 95 is provided in the floor of the base 94 on the impeller

axis, and cavities in the cover and base form a volute 96 which leads from the impeller to an air outlet 97. The cover and base 93 and 94 are joined by means of slotted tabs 98 which extend upwardly from the base to snap over stepped ribs 99, the tabs 98 being further located by fitting between parallel ribs on the cover 93. The joint between the cover 93 and the base 94 is sealed by an elastomeric sealing ring 101.

The bottom surface of the fan housing base 94 is provided with radial stiffening ribs 102, and overmoulded to the base 94 is an elastomer damping member 103 which covers that bottom surface between the ribs 102, and extends around the edge of the base by a flange portion 104 and peripherally spaced tabs 105. By overmoulding to the rigid plastics base 94 an elastomer of much lower stiffness and much lower density substantial acoustical damping is provided to the fan housing.

Moulded integrally with the rigid plastics portion of the fan housing base are feet 106 which extend through the overmoulded elastomer member 103 to receive helical mounting springs (not shown) by which the fan is mounted on the base 72 of the fan cavity.

The degree of size reduction which is an objective of the present invention requires great care to be taken to minimise the transmission of noise and vibration, particularly from the motor and the impeller of the fan 90. The mounting springs are therefore chosen to ensure minimal transmission of the vibration frequencies encountered during operation. This is achieved by choosing the springs with reference to the mass of the fan 90, such that the natural frequency of the system comprising the springs and the fan is at least approximately one tenth of the vibration frequency encountered when the motor is running at its lowest operating speed.

The air outlet 97, upon the introduction of the fan into the fan cavity, is connected by means of a thermoplastic elastomer coupling member 108 with an air passage 109 which extends from the side wall of the fan cavity to a connecting nozzle 110 extending through an aperture 111 provided for this purpose in the front face of the flow generator.

The fan 90 therefore floats within its cavity 70 in the chassis 64 with minimum acoustic coupling to the remainder of the flow generator. The characteristics of the mounting springs and the coupling member 108 are chosen to minimise the transmission of characteristic vibration frequencies of the fan.

The air outlet passage 109 is formed in the roof of the upper part of the resonator cavity 68. Holes 112 communicating with the resonator cavity are provided in the floor of the passage 109 where it crosses this cavity, which acts in the manner of a Helmholtz resonator. By adjusting the dimensions and number of the holes 112, the frequency response of the resonator can be adjusted for optimum noise cancellation. If desired, a second Helmholtz resonator cavity can be provided opposite the cavity 68, if the dimensions of the upper case allow this.

The novel use of Helmholtz resonators for noise attenuation contributes to the success in achieving significant size reduction in the flow generator of the present invention.

As shown in Fig. 12, the humidifier 150 comprises a base unit 151 designed for simple attachment to and detachment from the flow generator 50, and a tank 152 which is similarly attachable to and detachable from the base unit.

The rear face of the base unit 151 has a peripheral flange 153 which seats in a corresponding peripheral recess 113 surrounding the front face of the flow generator 50 when the two units are brought together by linear movement towards each other. The tongues 156 are moveable vertically and resiliently urged downwardly, so that these tongues engage in the slots 55 and snap home to engage the two units by means of the downwardly extending fingers 158 at the ends of the tongues.

An air flow passage 160 passes through the rear face 157 and opens to the front wall of the base unit. This passage is surrounded at the rear wall with a cylindrical connecting portion 161 which receives the nozzle 110 of the flow generator upon

engagement of the two units. The inner surface of the portion 161 is provided with a sealing device such as a layer of elastomer or other soft resilient material.

The rear face of the base unit also carries a connector 162, in this embodiment a pair of flat male blade connectors, for engagement with a mating connector 114 on the front face of the flow generator, to provide power to the humidifier heater from the power supply in the power supply cavity 65. Although not shown in the illustrated embodiment, the respective faces may also carry further interconnecting devices, where other electrical or data connections are required to be established between the flow generator and the humidifier or downstream devices including the air conduit or the mask. Such devices may take the form of optically coupled devices, or connectors of other suitable kinds.

The use of such an opto-coupling connector enables the implementation of a simple protocol for communications between the flow generator and the humidifier. For example, the current flow levels of the flow generator can be sent to the humidifier controller which then adjusts the operation of the humidifier according to a predetermined algorithm.

Within the humidifier base unit 151 but not shown here is provided a variable power supply for a heating element which heats a circular metal pad 163. A control knob 164 is provided on the upper surface of the unit for adjustment of the heat supplied to the pad 163. A semicircular wall 165 surrounds the rear part of the pad 163, and carries at its upper edge an inwardly directed flange 166. The pad 163 stands proud of the surrounding base surface 168.

It will be observed that the air passage 160 opens to the front face of the base unit at the foot of a circular recess 167 of larger diameter, corresponding to the diameter of the tank inlet 175 described below. The effect of this is to provide a vertical offset between the air passage 160 and the inlet 175, with the former lower than the latter in the normal orientation of the unit. This configuration assists in the prevention of

backflow as will be described below. It is to be observed that the axial offset in question could be achieved in other ways.

The recess 167 is provided with a sealing layer of elastomer or other sealing material.

The tank 152 comprises a cover 170 which is preferably of a transparent plastics material, a metal base 171 preferably of stainless steel, a base flange 172 which functions to couple the cover and the base, and a sealing gasket 173 which locates between the base of the cover and the metal base 171.

The periphery of the base flange 172 is dimensioned to slide into engagement with the wall 165 of the base unit and beneath the flange 166 to engage the tank with the base unit, and the tank cover 170 is provided with a cylindrical air inlet 175 extending from its side wall. The inlet 175 is dimensioned to fit sealingly within the recess 167 when the tank is engaged with the base unit as described above and as shown in Fig. 3. An air outlet 176 extends upwardly from the roof of the cover 170 for connection with an air hose for the delivery of humidified air to the patient.

The metal base 171 seats within the base flange 172 which is provided with a central aperture, so that the bottom of the metal base 171 is exposed to contact the heating plate 163 when the tank is engaged with the base unit. The metal base 171 is thus heated by the heating element of the base unit. To assist in achieving good heat transfer between the heating plate 163 and the base 171, the former is resiliently biased upwardly, for example by means of a spring or springs (not shown). This has the further advantage of providing for positive retention of the tank in the base unit, by providing around the central aperture in the base flange, a downwardly directed rim (not shown) which will initially depress the heating plate as the tank is moved into position on the base unit, and which forms a central space into which the heating plate moves under its spring pressure, upon full engagement of the tank with the base unit.

In alternative embodiments not illustrated here, the tank may be provided with locking detents for retention on the base unit.

The lower edge of the cover 170 and the inner edge of the base flange 172 are provided with bayonet type engagement formations 177 and 178 respectively, so the tank components can be assembled and disassembled simply by relative rotation of the cover and the base flange. To assist in this operation, a peripheral groove 179 is provided in the base of the base flange 172, and this groove is interrupted at intervals by finger-engaging bridges 180. The inner wall of the groove 179 protects the user's fingers against accidental contact with the metal base 171, in case removal of the cover is carried out while the base is still hot.

The tank is intended to be filled via the air outlet 176, and the apparatus may be provided with a filling bottle with a spout dimensioned for a convenient fit with that outlet. Such a bottle may be provided with a spout of the kind incorporating an air bleed passage which will allow the tank to fill to the correct predetermined height. In alternative embodiments, other filling arrangements may be employed. The correct filling height is also indicated by filling level graduations 184 scribed or otherwise marked on the wall of the cover 170.

As will be seen in Fig. 16, the air inlet 175 of the cover 170 extends within the cover in the form of an arcuate passage 181, to open to the interior of the cover at a point beyond, in the direction of air flow, the outlet 176. The open end 183 of the passage 181 is directed obliquely towards the inner wall of the cover. The outlet 176 is, furthermore, between the convexly curved side 182 of the passage 181. This configuration has several important consequences.

Firstly the curvature of the passage 181 and the oblique orientation of its outlet 183 will induce a swirling action on the air mass within the tank, as the air moves around the tank to escape from the outlet 176. This swirling action will enhance the uptake of water vapour from the water contained in the tank.

Secondly the configuration minimises the risk of water from the tank flowing back into the air inlet passage should the tank be tilted while containing water. Whenever

the orientation of the tank is such that the air outlet is below the air passage opening 183, water will flow into the air outlet before it will flow into the inlet passage, and whenever the air outlet is above the opening 183, then except in the case of inversion of the tank, water will not escape via the curved passage 181 unless the tank has been filled with a volume of water which is greater than that which is contained within the sector of the tank below a tangent to the convex surface of the passage 180. This can be avoided by appropriate setting of the height of the fill line 184.

Should water escape into the passage 180 due to inversion of the humidifier while it is engaged with the flow generator, its path to the air passage 160 will be blocked by the dam formed by the face of the recess 167, which will then be below the passage 160.

Fig. 17 shows a modified form of tank cover in which a downwardly extending wall 187 is provided across the end of the arcuate passage 180, this wall extending in a curved wall 188 beyond the opening 183. The curved portion 188 assists in the formation of a swirling air flow within the tank, while both walls 187 and 188 tend to protect the opening 183 against wave action within the tank during transport.

If desired, further security against backflow can be provided by locating a non-return valve at an appropriate point. An example of this is shown in Fig. 14, where a valve comprising a flexible membrane 185 supported on a spider 186 is placed in the mouth of the humidifier air inlet 175.

In the illustrated embodiment the curved passage 181 is shown as a low profile passage of substantially rectangular cross-section. An alternative approach is to continue this passage as a cylindrical passage having a diameter similar to that of the air passage leading from the flow generator to the humidifier. The advantage of this will be to avoid the introduction of impedance to the flow of air through the humidifier. Generally speaking it is desirable to minimise pressure drop through the humidifier, to avoid interfering with diagnostic or monitoring functions in the flow generator, for example the detection of snoring, which require the detection of sound transmitted back through the system from the patient.

The enhanced uptake of water vapour achieved by inducing the swirling of air as it passes through the tank enables, in an alternative embodiment of the invention, the elimination of the heating of the water in the tank 152. In such an embodiment the heating element and its controls, and the heat transfer components including the heating plate 163 and the metal tank base 171 are eliminated, and the humidifier becomes a simpler, passive, device.

Figs. 18 to 21 show various forms of modular data connections foreshadowed earlier, utilizing the slot 83 in the rear of the flow generator housing.

The slot 83 is provided in the wall of a rectangular recess 115. An arcuate depression 123 is provided in the upper surface of the unit above the recess 116 to facilitate removal of closure elements from the depression, as described below.

Where the flow generator in question is not intended to be employed with any data connection, the slot 83 is closed off by a blank closure element 117, shaped to fit into the recess 115. This element snaps into the recess by means of lower tabs 118 and an upper tab 119 which fit corresponding depressions such as 122 in the walls of the recess 116, to close the slot 83 and conform to the contours of the surrounding surface of the unit.

Complementarily shaped closure elements can be provided for the reception of different kinds of data devices. Shown in Fig. 20 is an element 116a provided with a slot for the reception of a smart card 120. The element 116a or the printed circuit board itself may carry the necessary smart card socket. Shown in Fig. 21 is an element 116b provided with a DB type data socket. In this case the element 116b is contoured to provide a lower front recess 121 to facilitate gripping of the associated plug.

Other forms of element 116 can be provided to enable the connection of devices such as memory cards and pre-programmed devices as required. This facility furthermore enables a wide range of devices to be integrated with the apparatus in modular

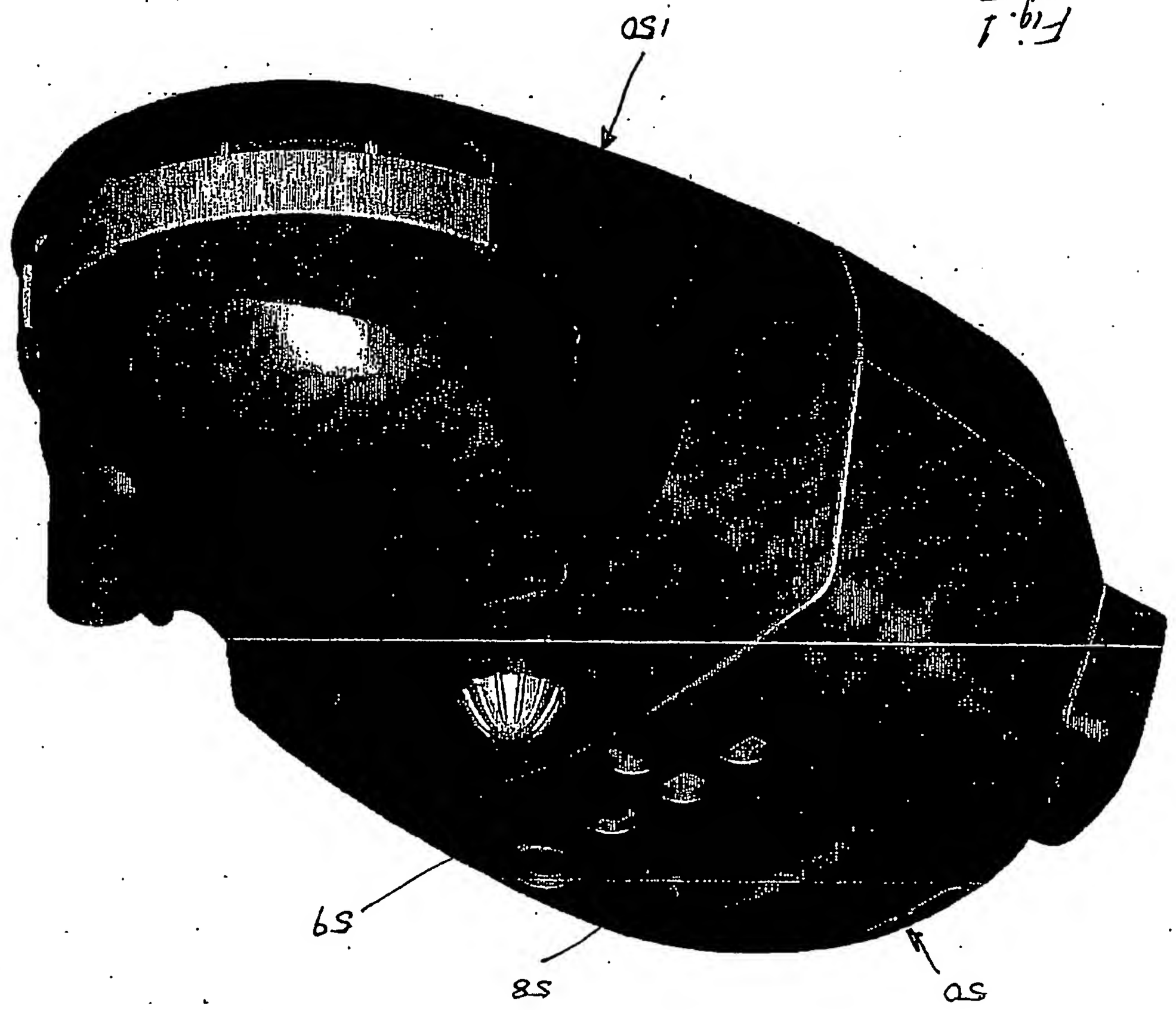
fashion, for example a clock display which may utilise the system clock contained in the flow generator controller, a voice activation unit, oximetry, ECG and other diagnostic aids, a sound recorder, a light.

5 It is emphasised that the forgoing disclosure has sought to describe many innovations in flow generator and humidifier design, and it is foreshadowed that these will be the subject of separate claims to protection in applications claiming the priority of this document.

10 DATED this 20th day of June 2003

ResMed Ltd
Patent Attorneys for the Applicant:
HALFORD & CO

Fig. 1



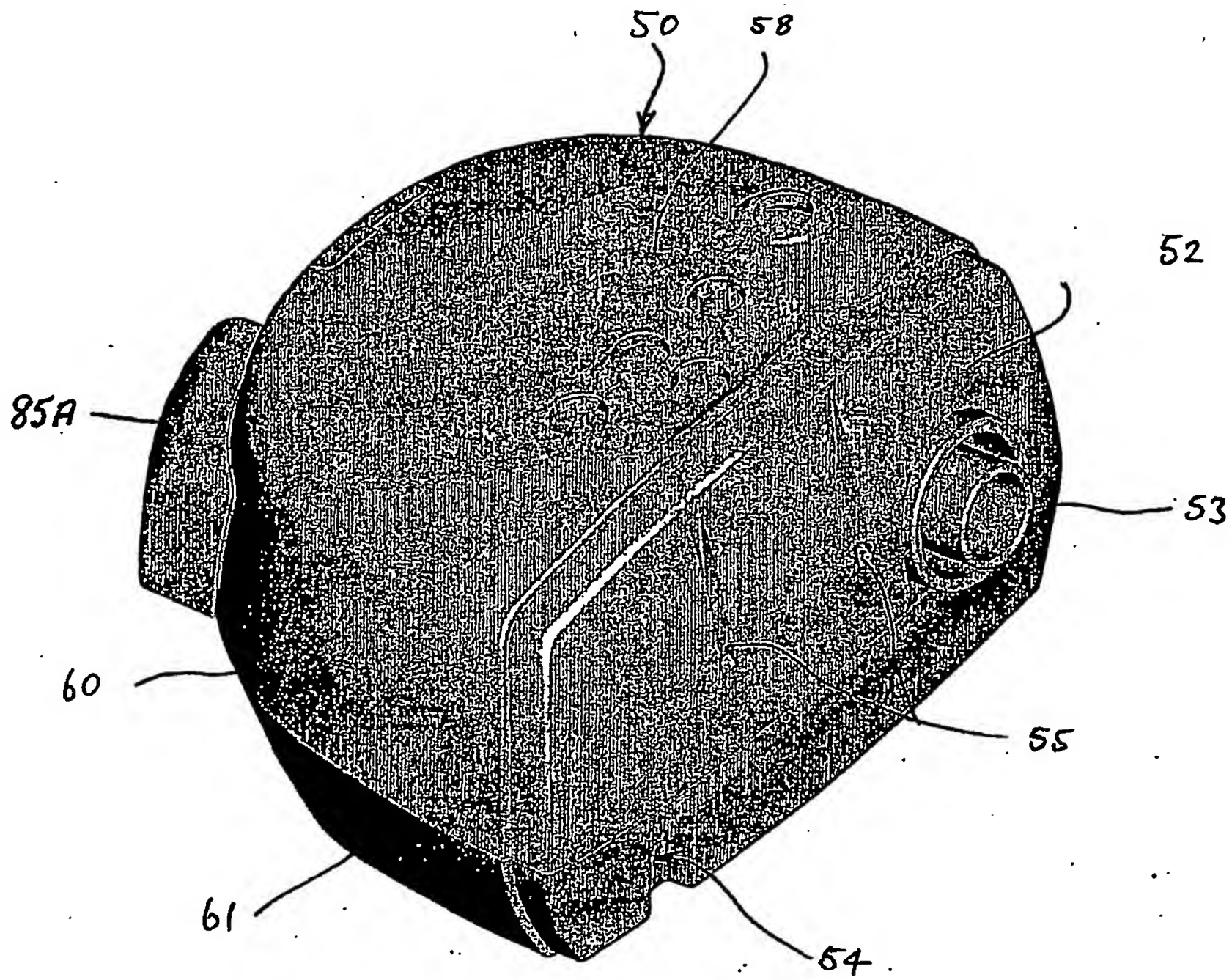


Fig. 2

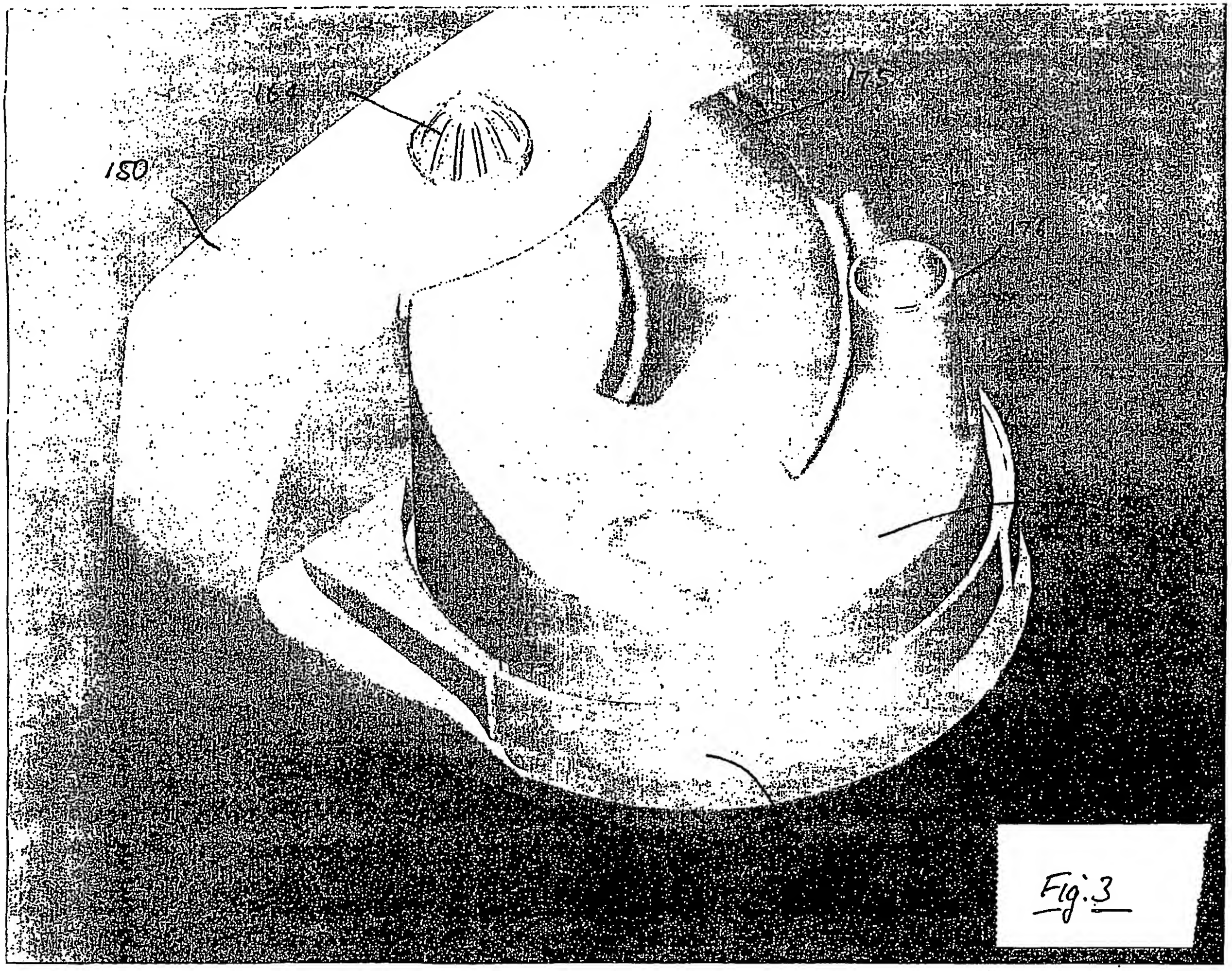


Fig: 3

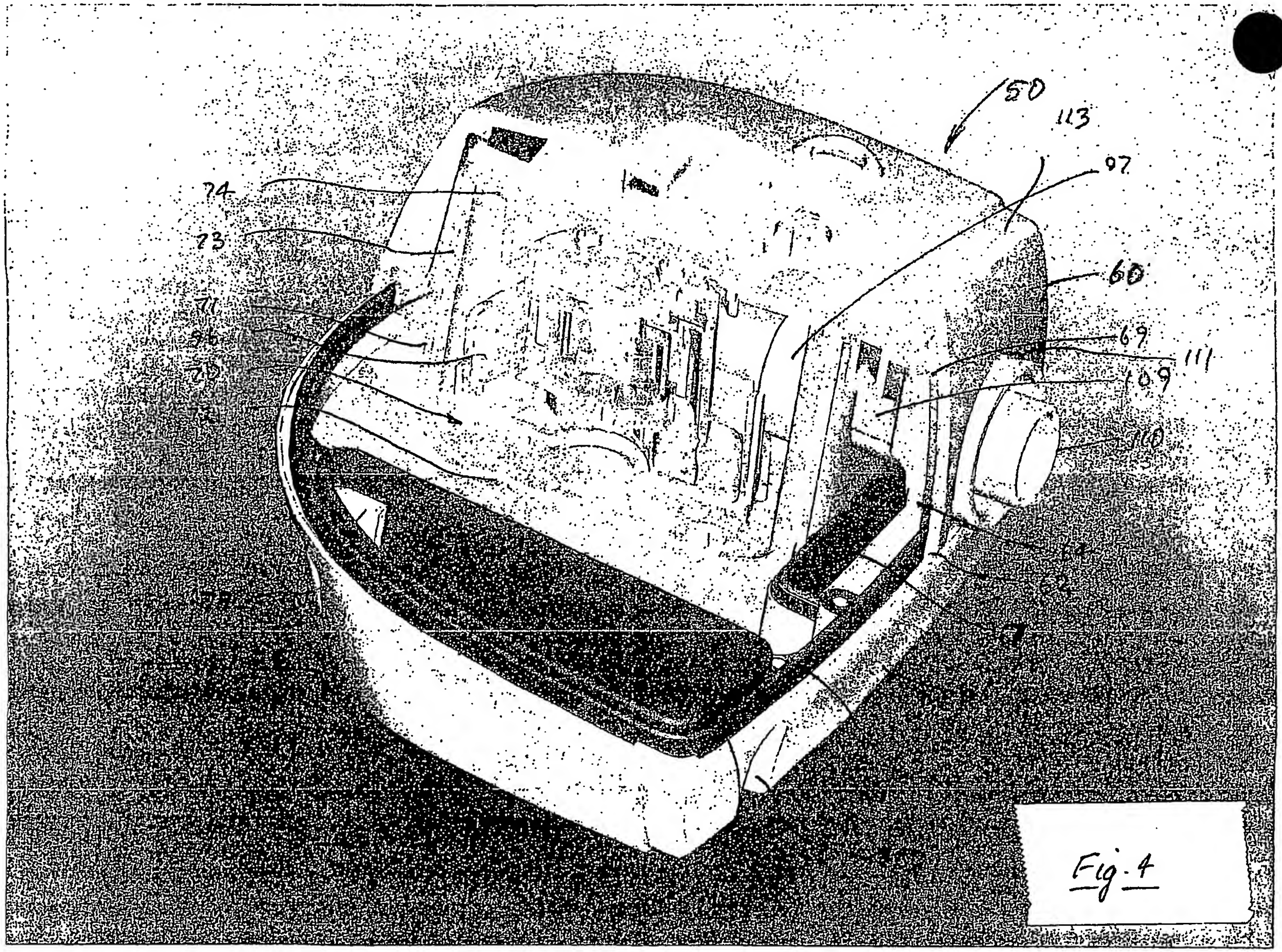
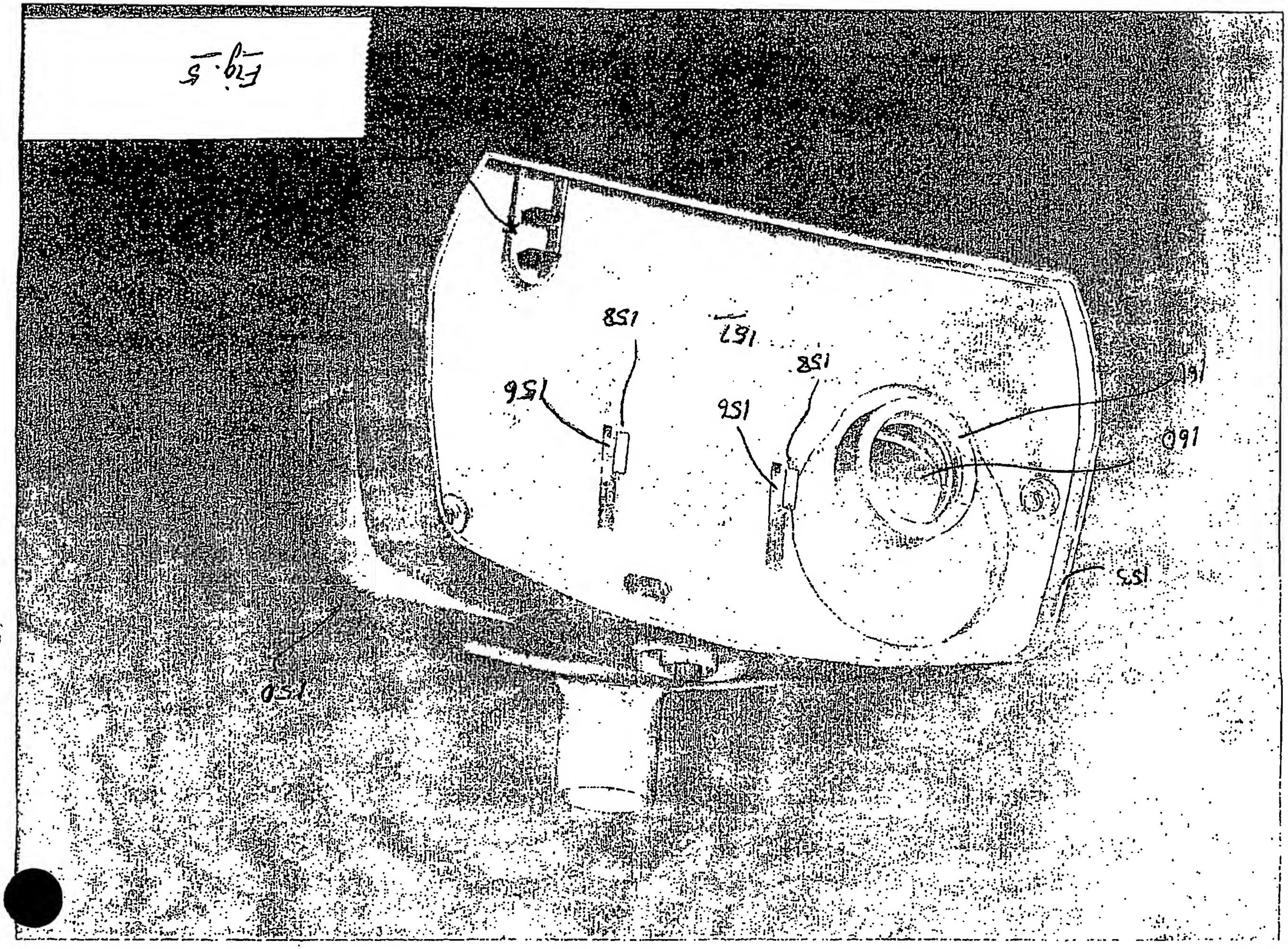


Fig. 4

Fig. 5



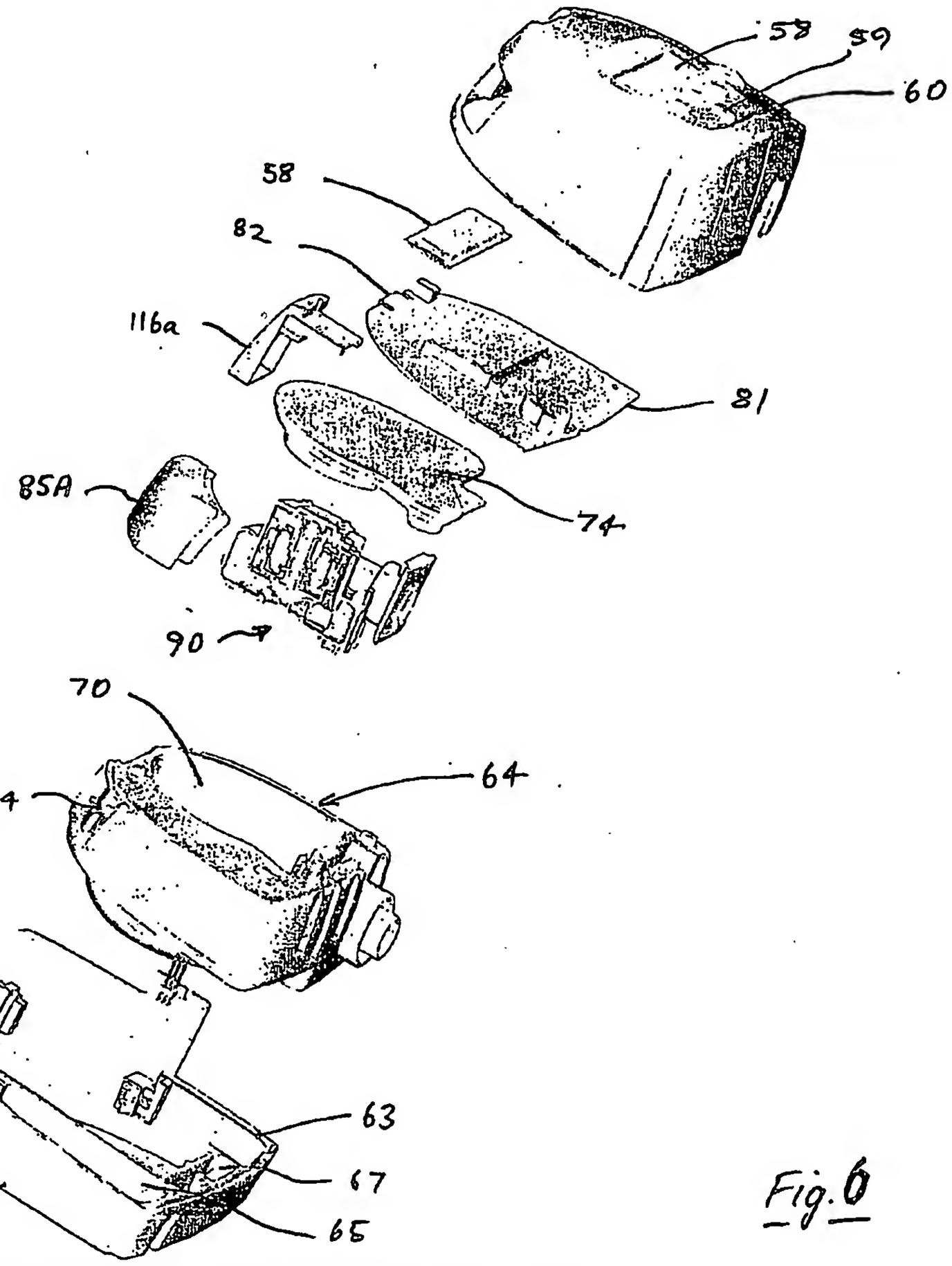


Fig. 6

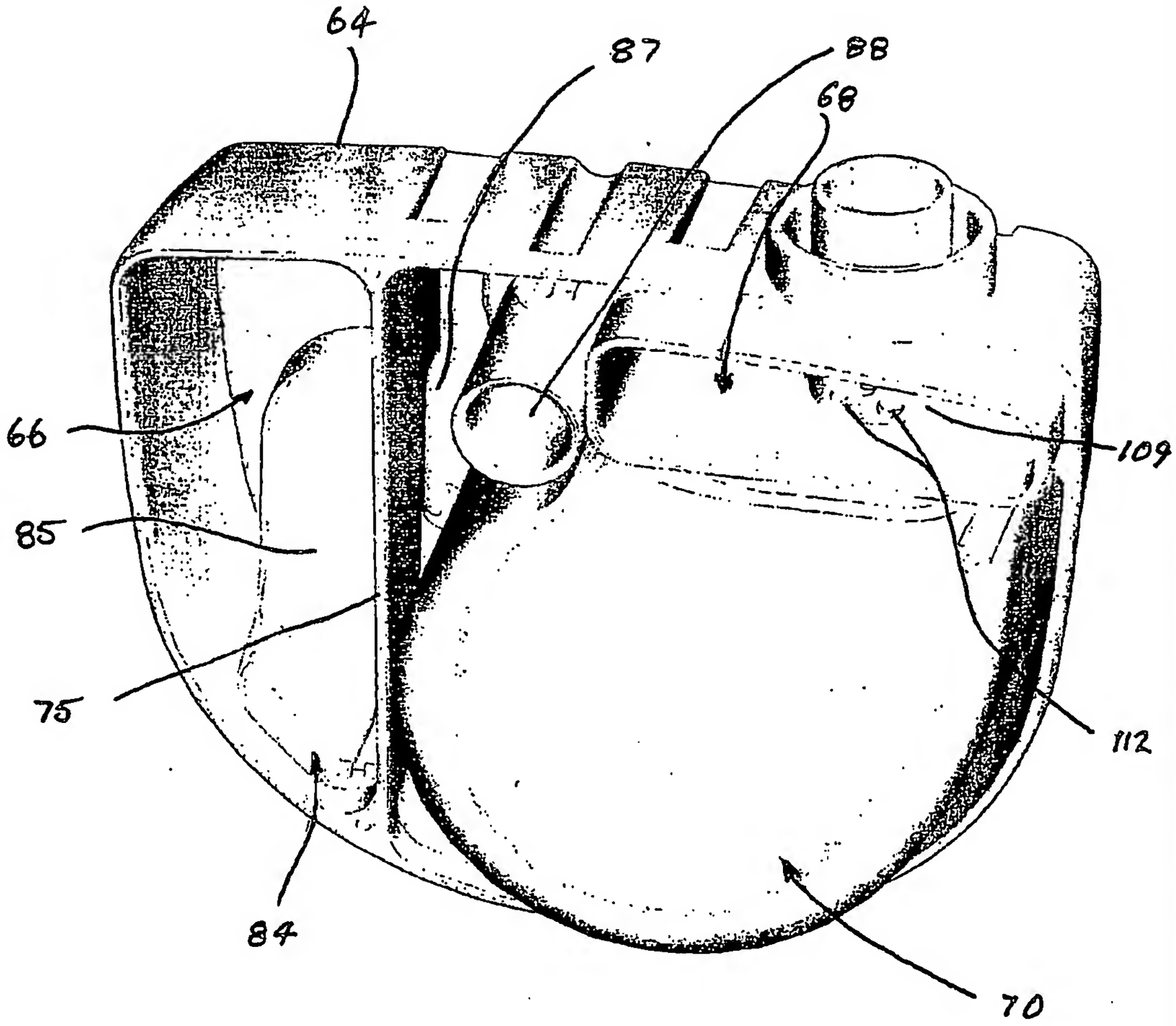


Fig 1

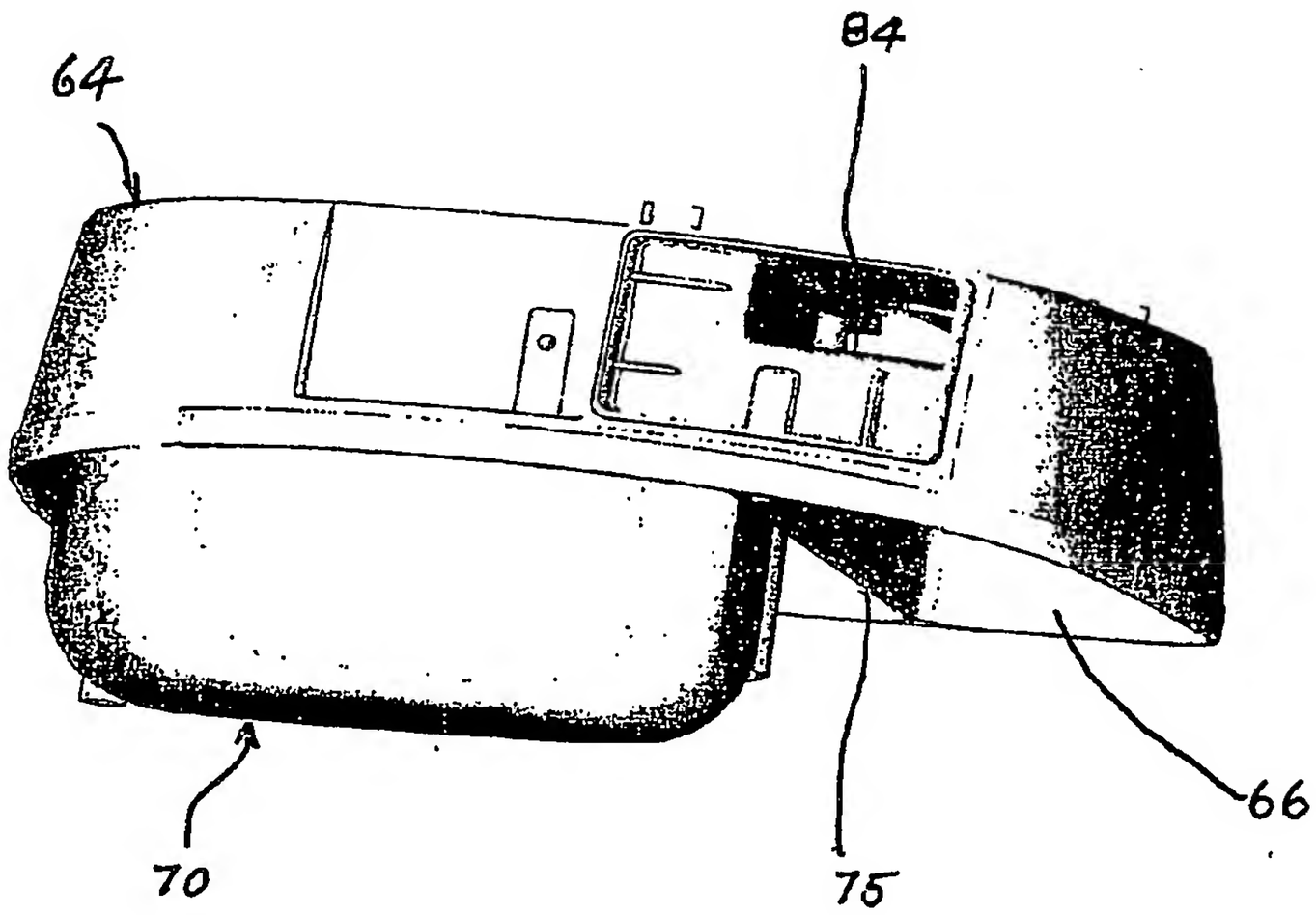


Fig. 8

Fig. 9

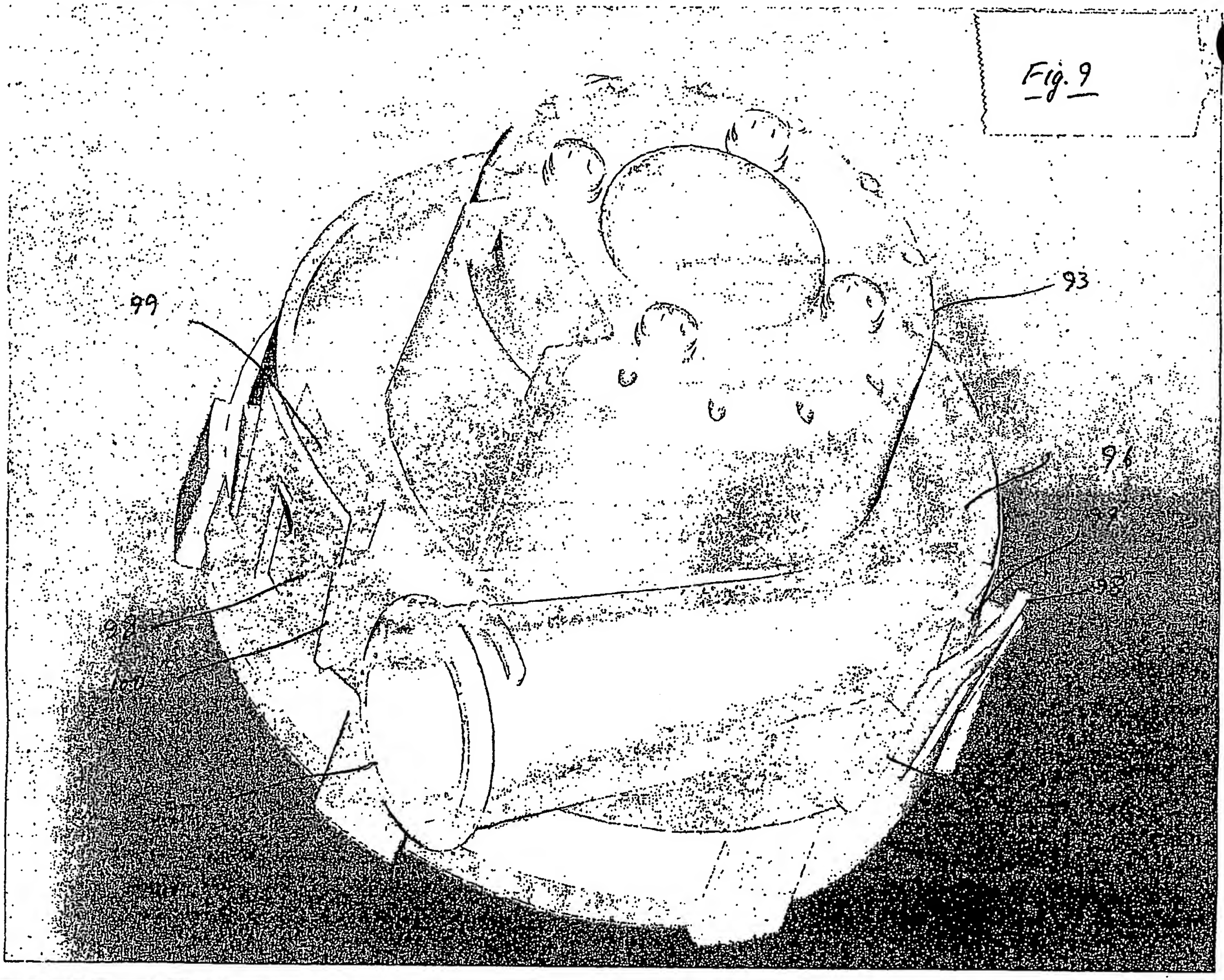


Fig. 10

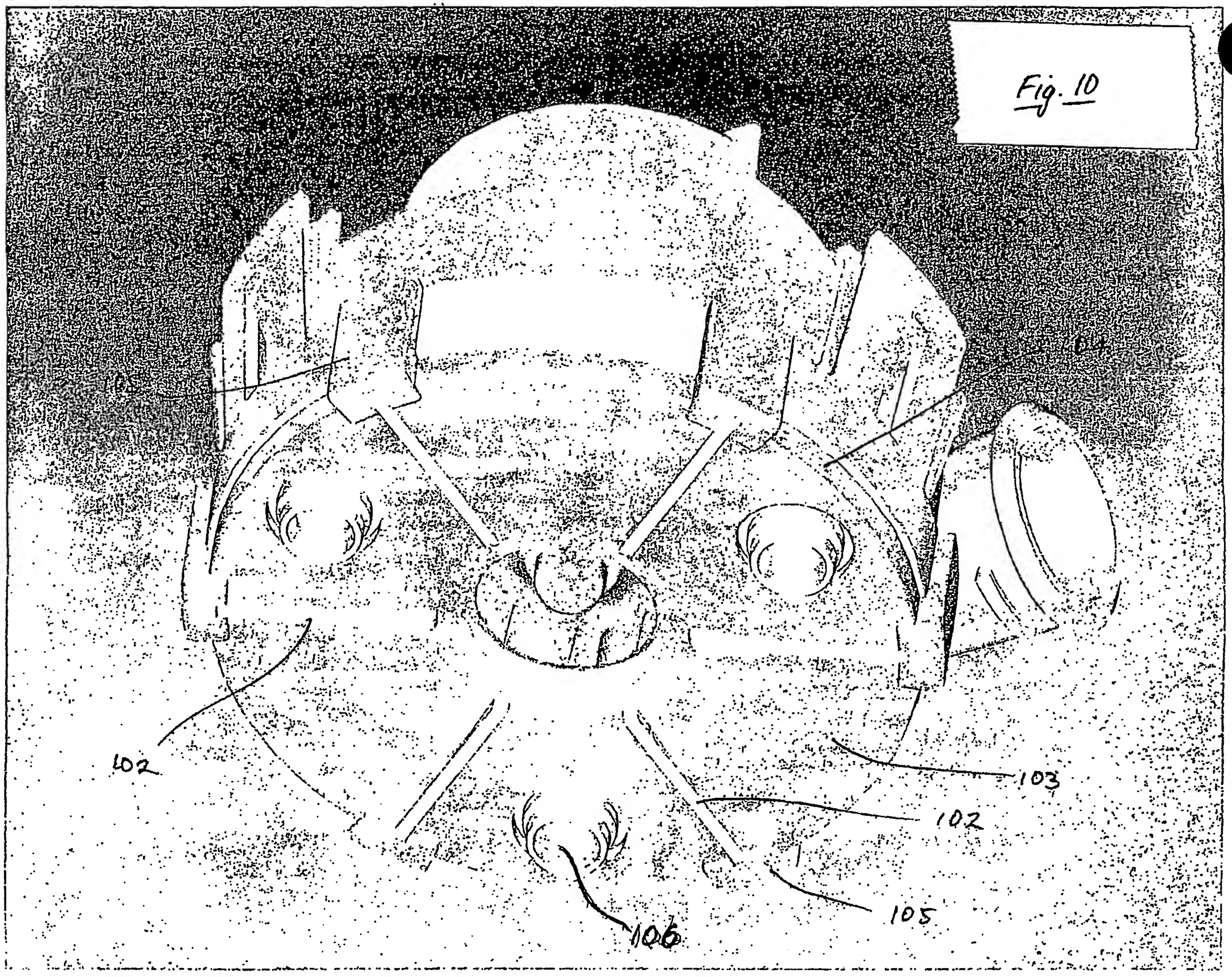
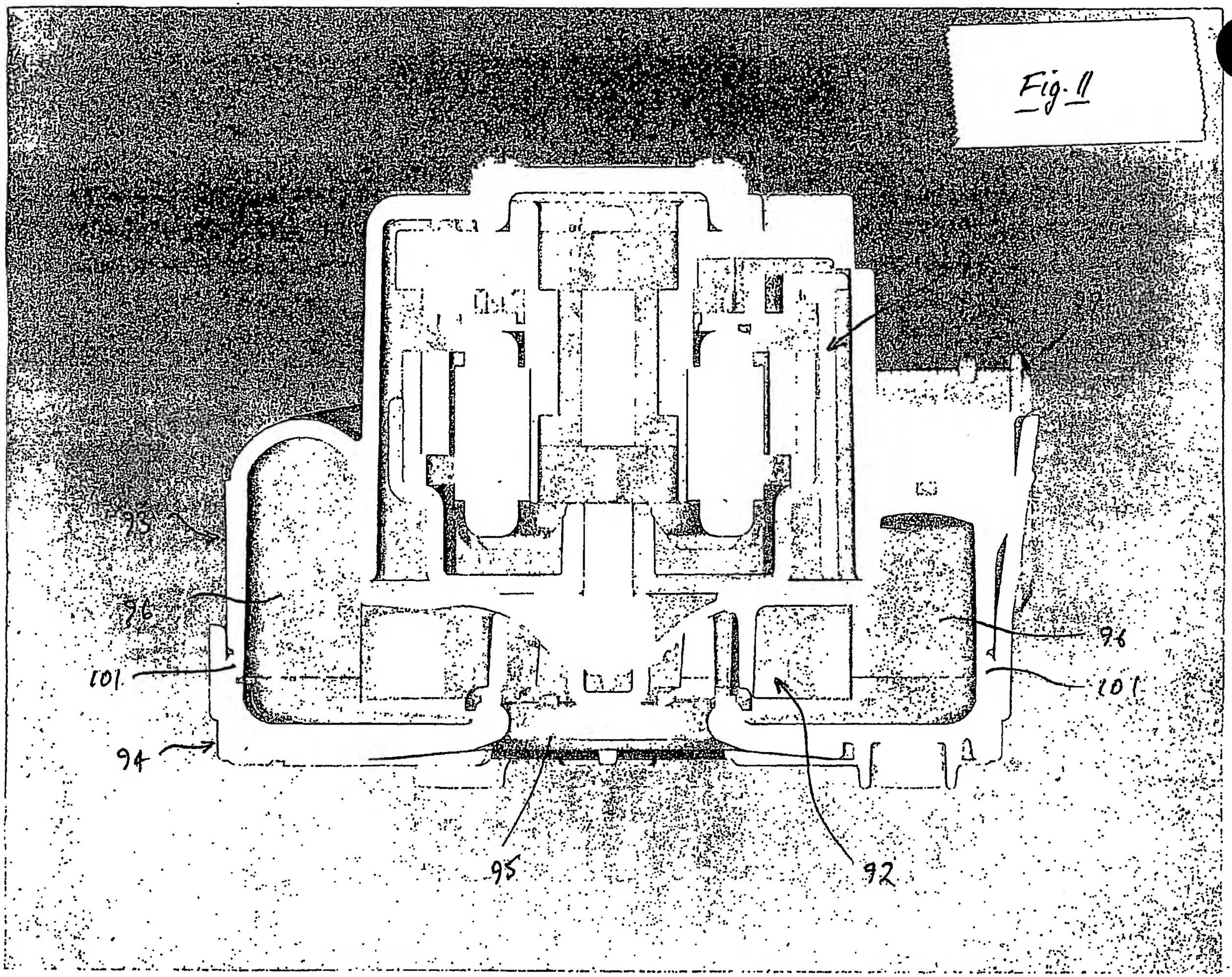


Fig. 11



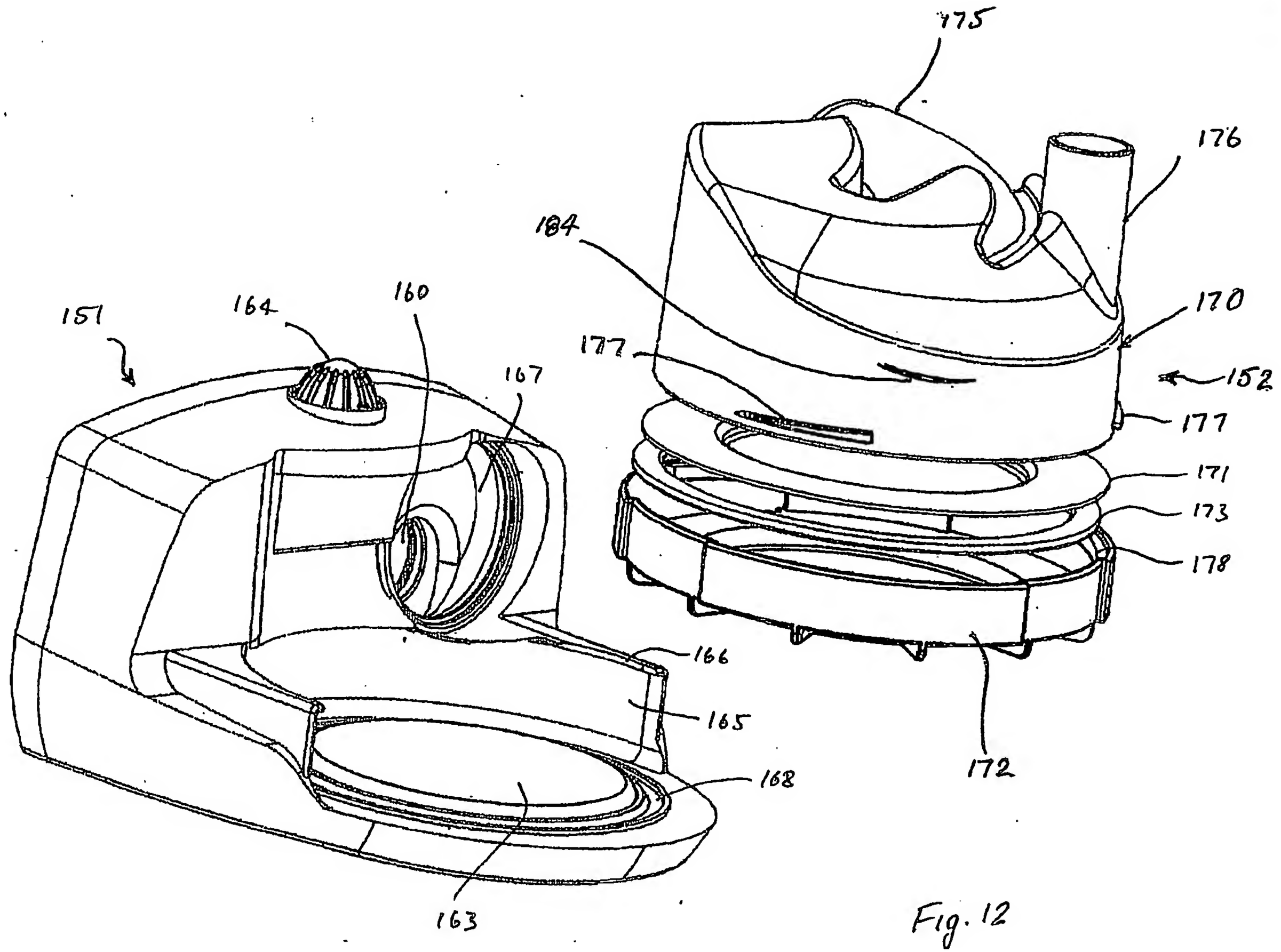

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Fig. 12

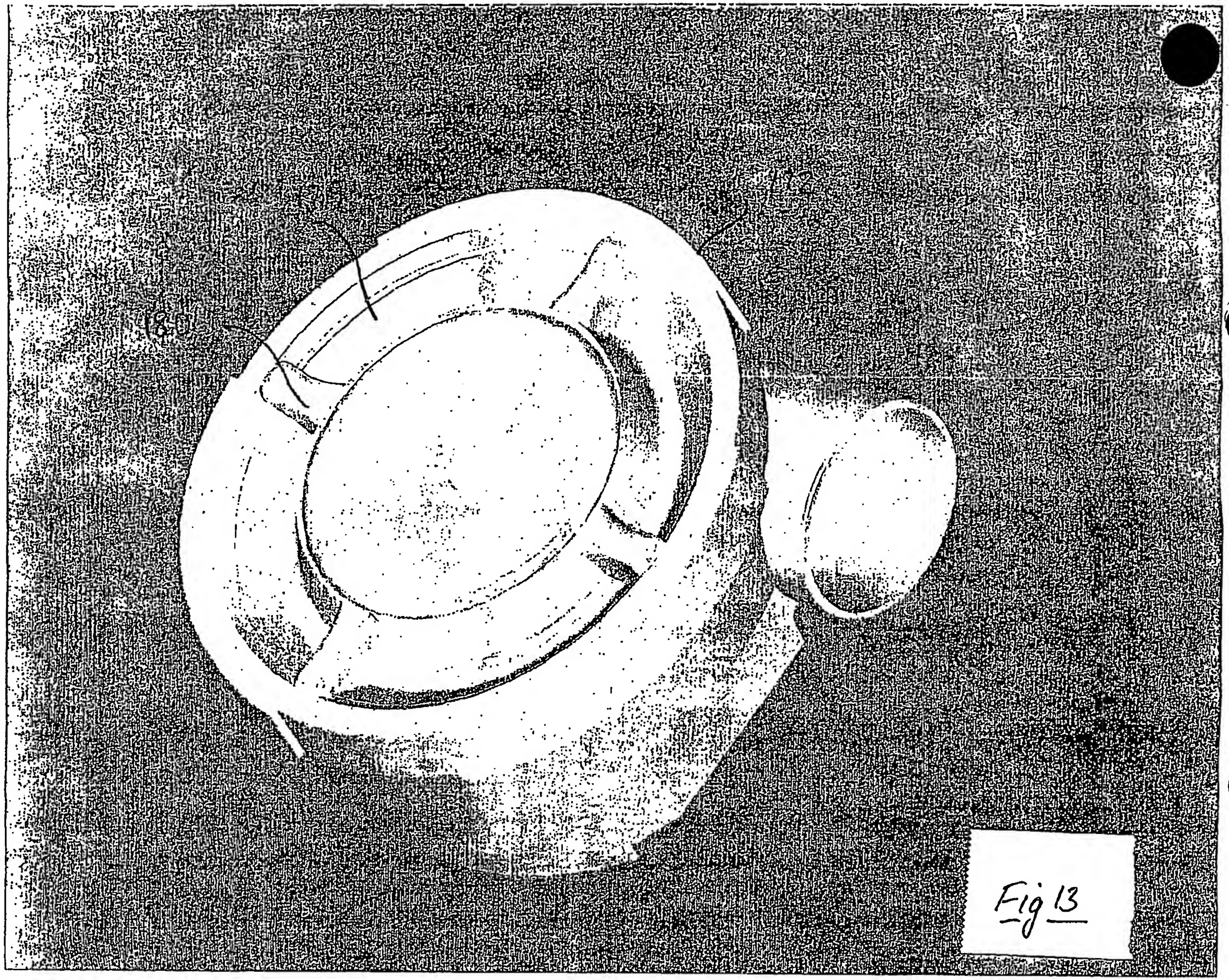


Fig 13

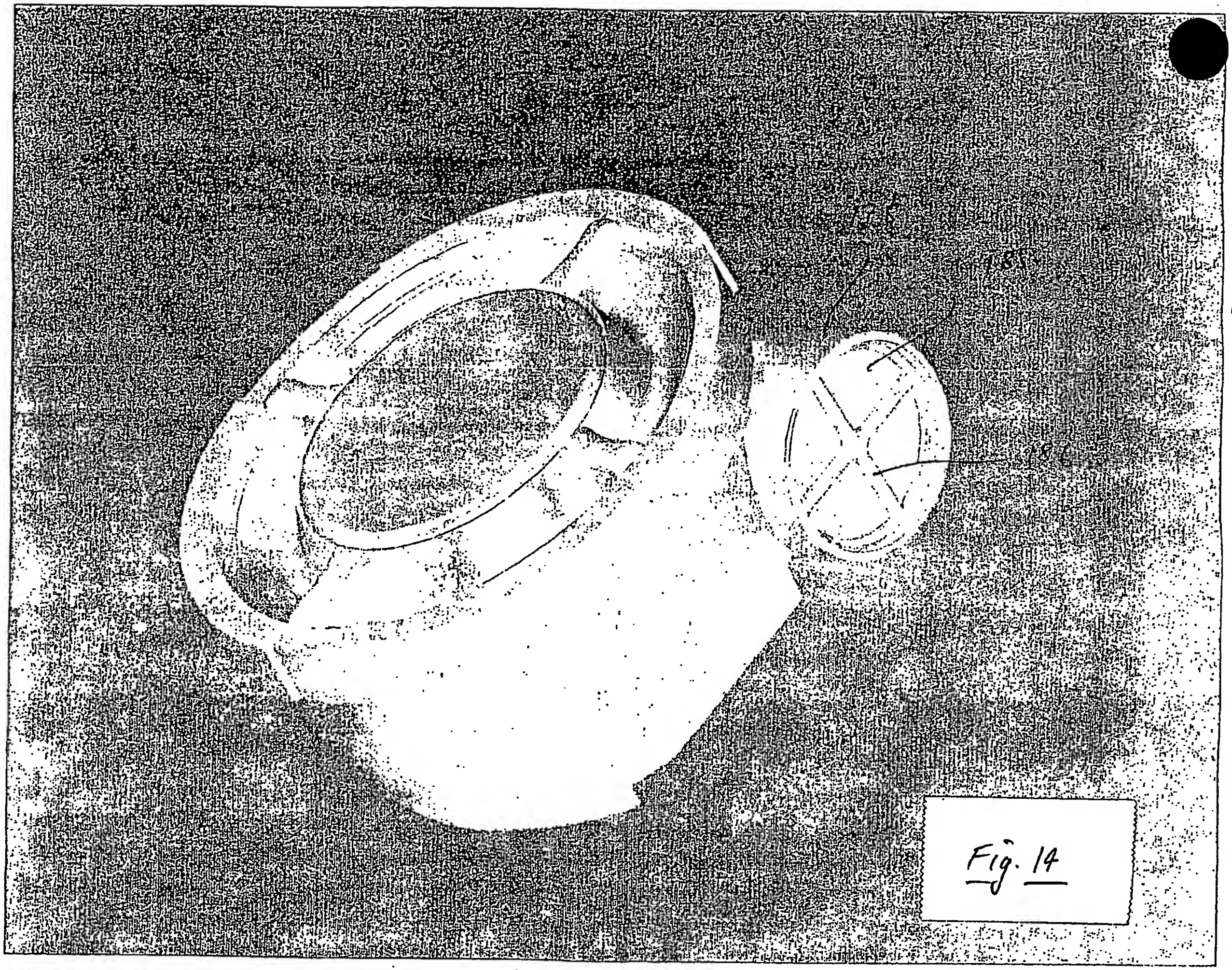


Fig. 14

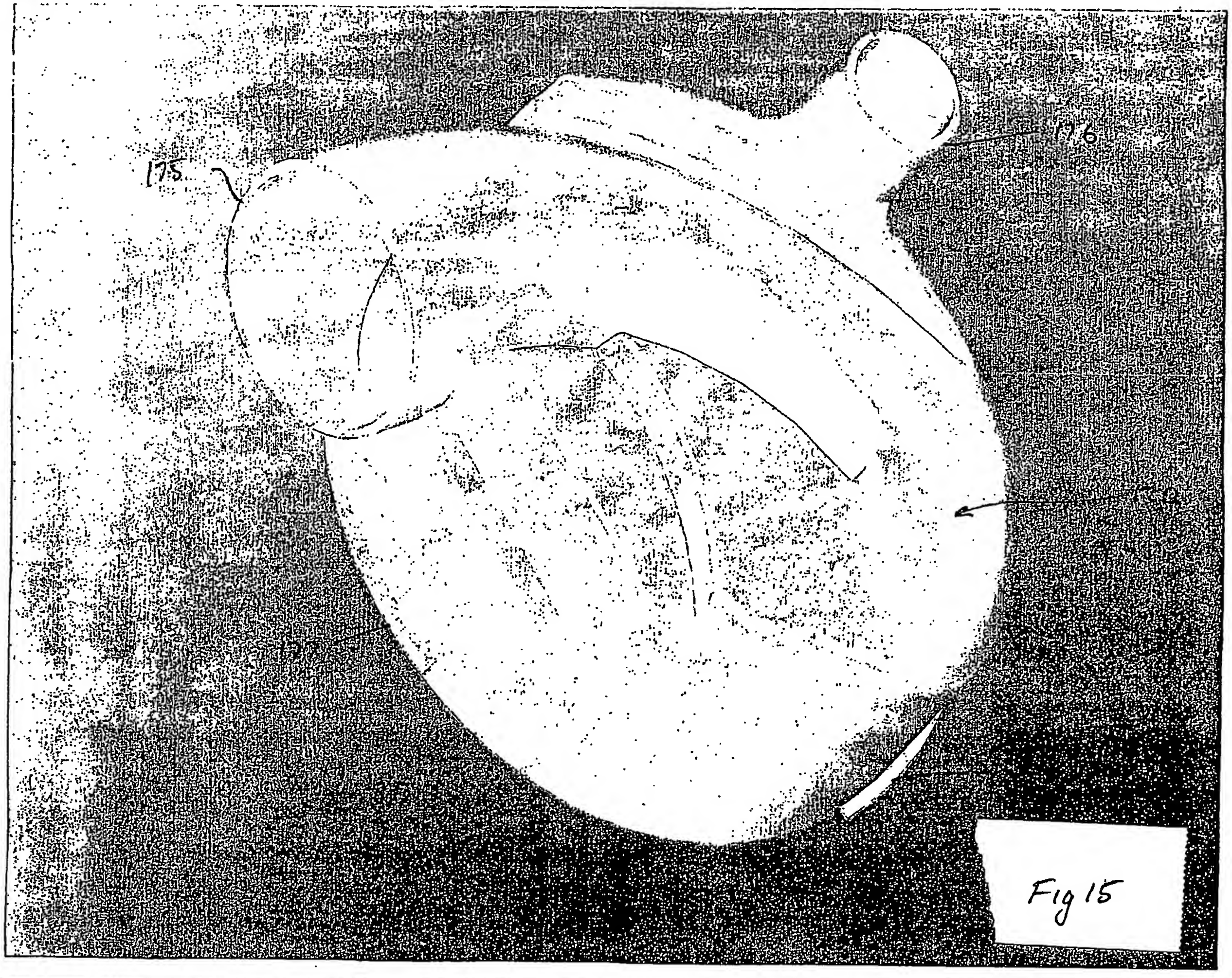
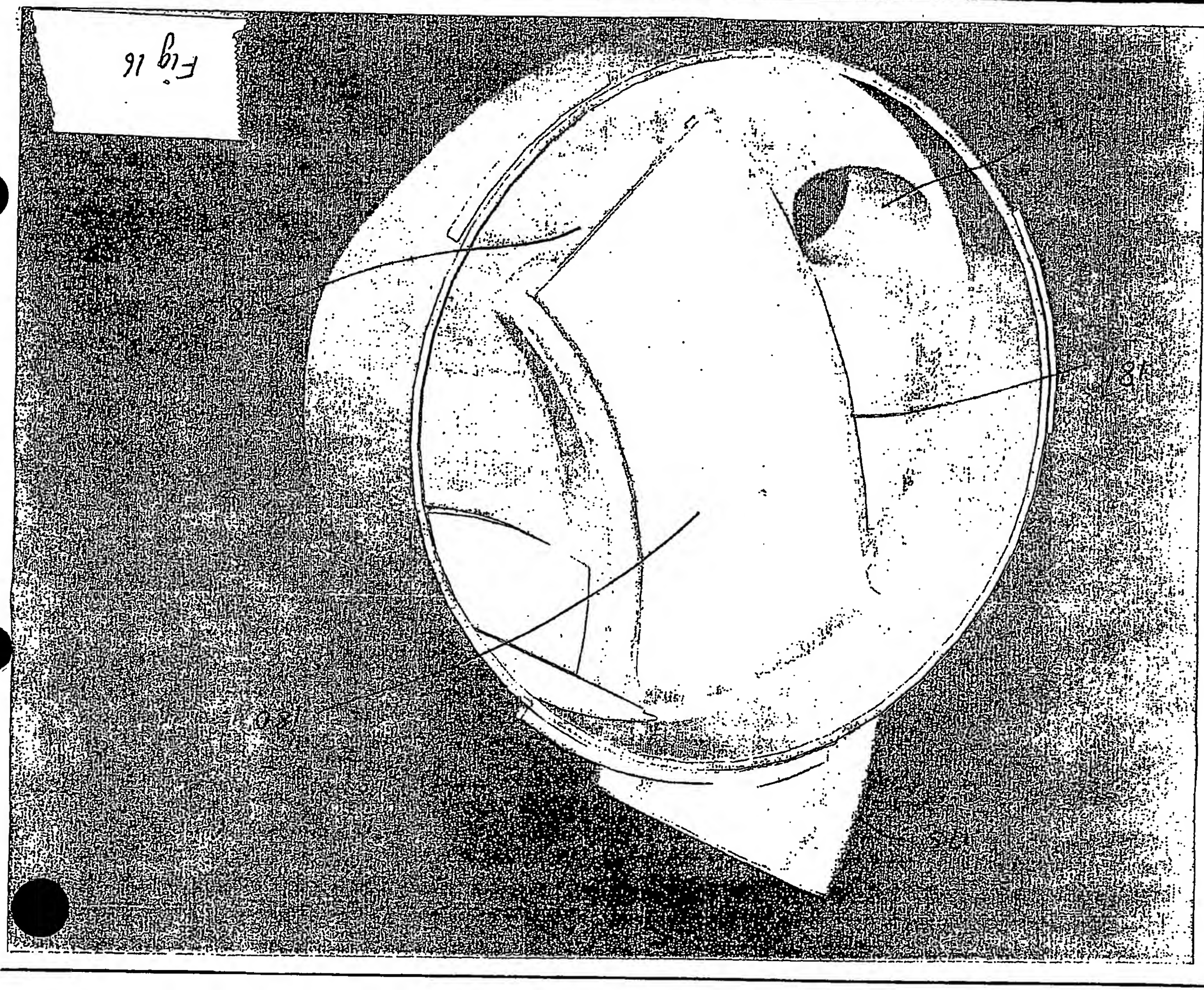


Fig 15

Fig 16



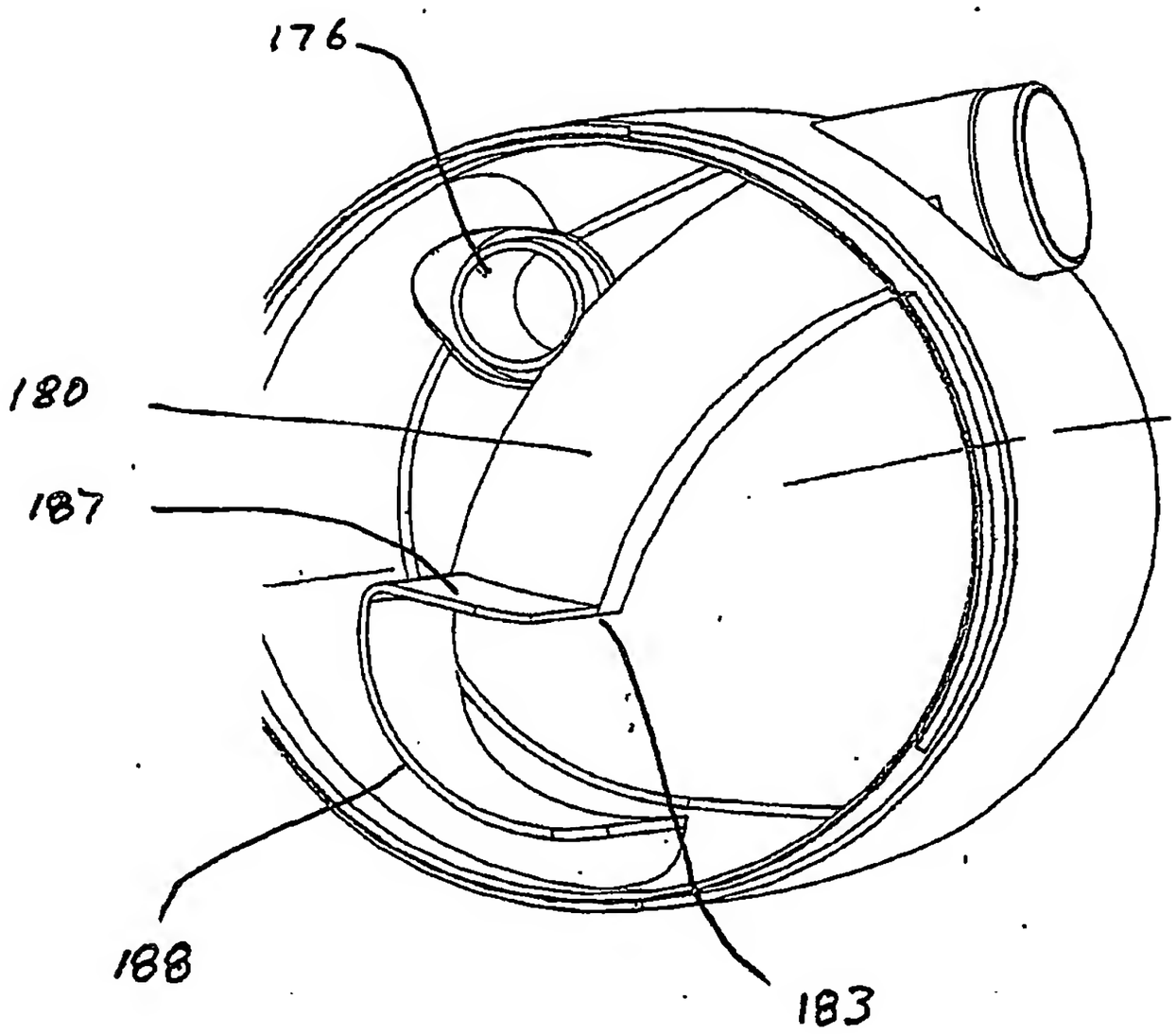


Fig. 17

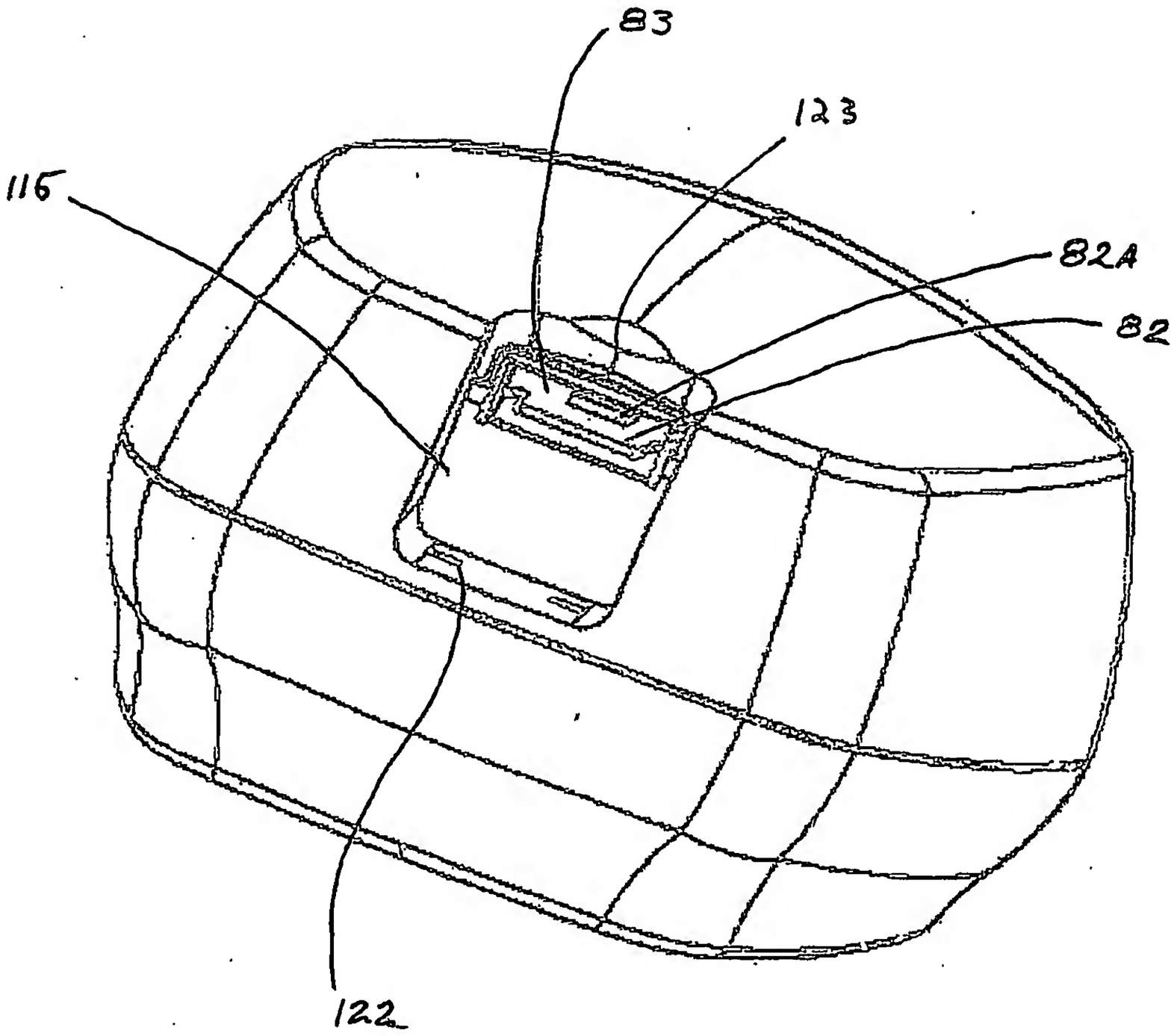
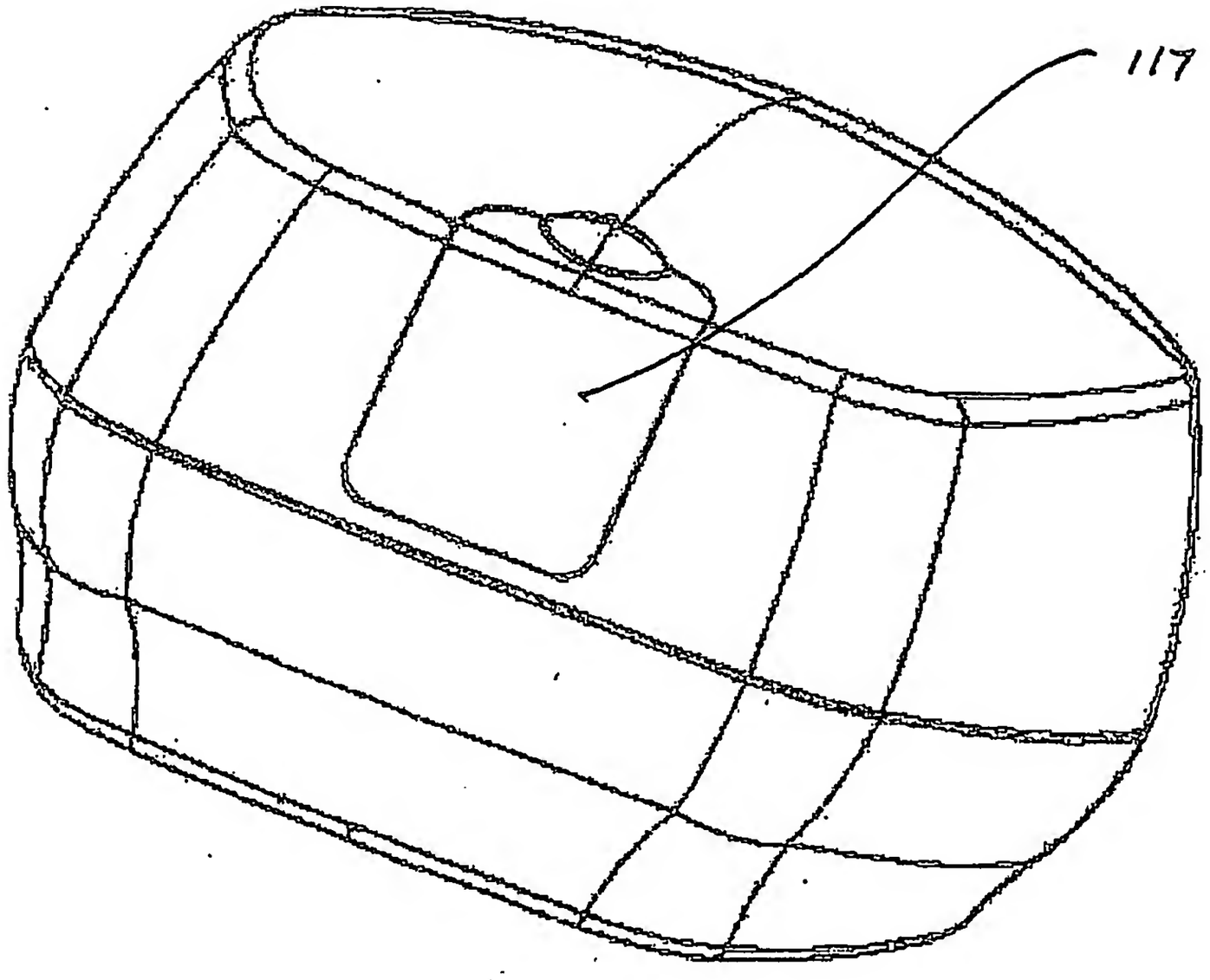


Fig. 18



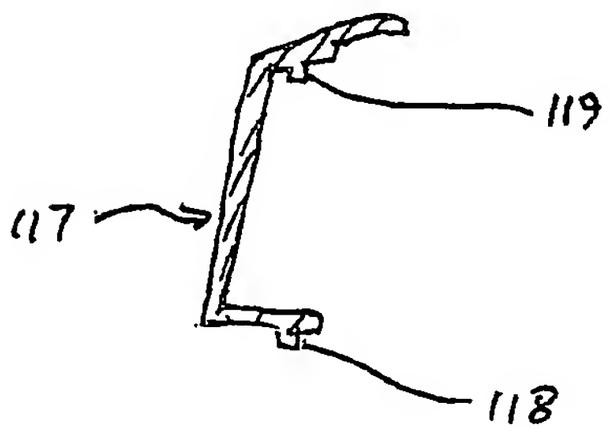


Fig. 19

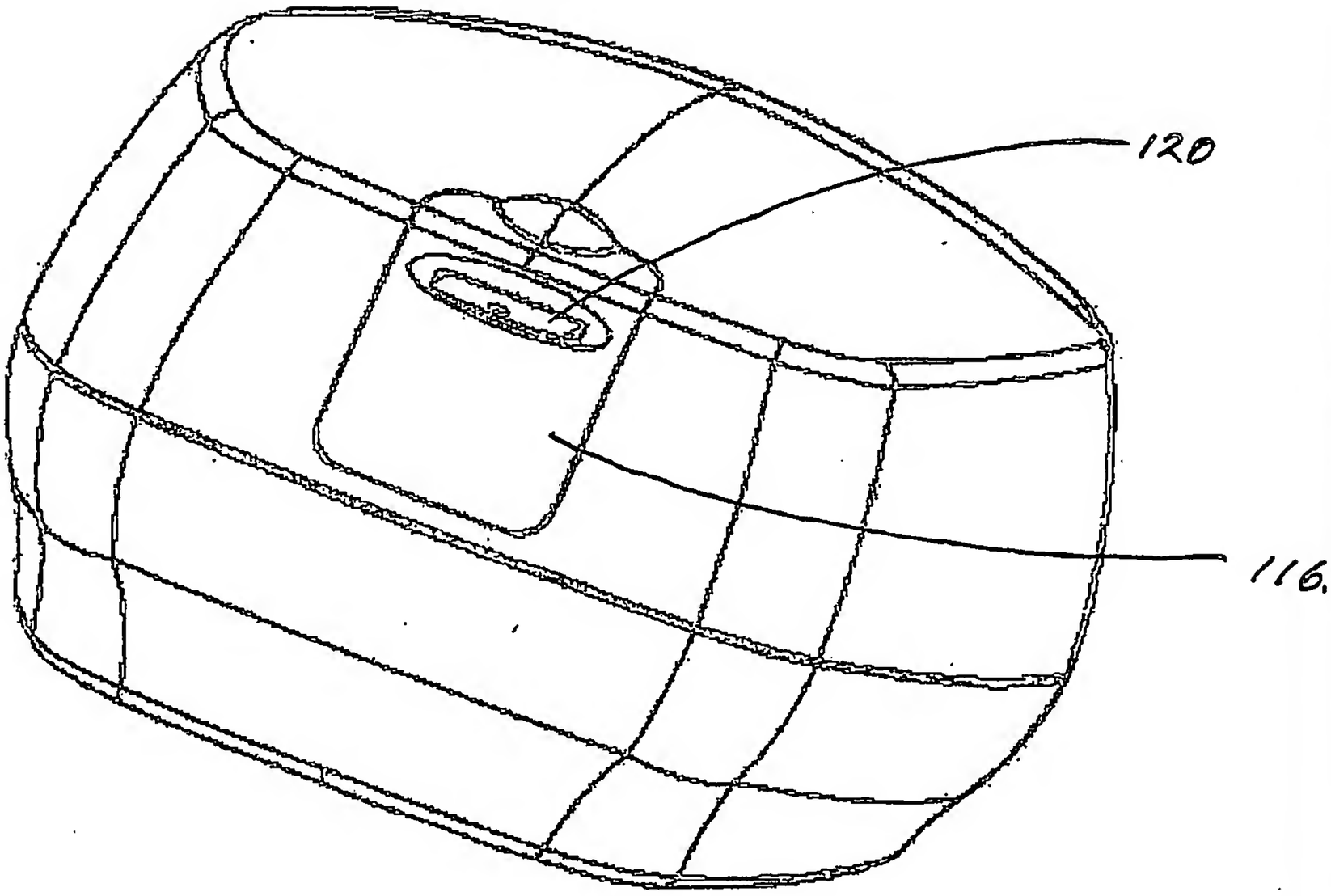


Fig. 20

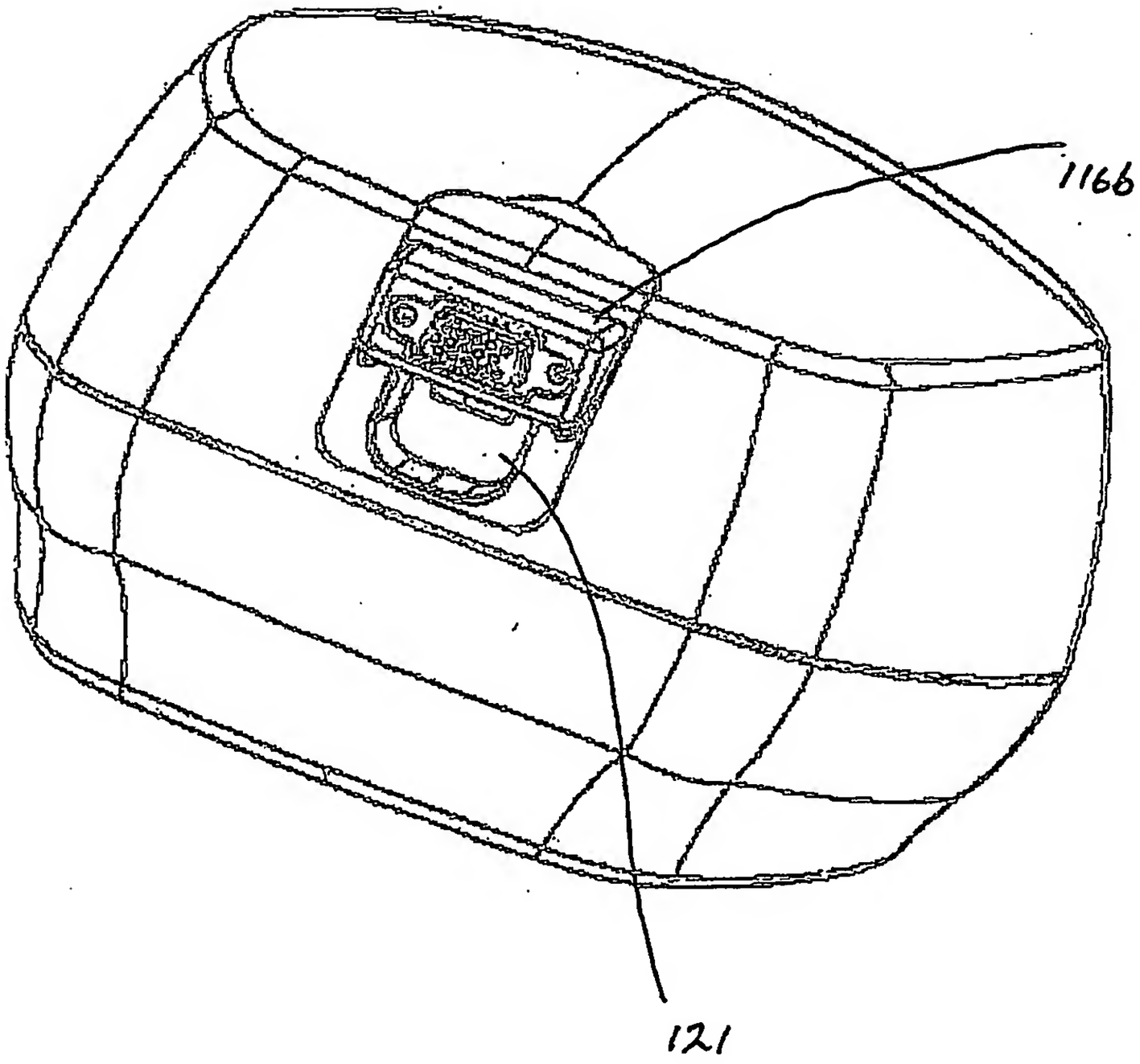


Fig. 21